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CLINICAL RESEARCH IN THE DEVELOPING WORLD TOWARDS A CONSENSUS FRAMEWORK FOCUS ON PROVISION OF POST-TRIAL CARE IAS-ILF PROGRESS REPORT 2002-2003

Since its inception, the Industry Liaison Forum has established itself as one of the flagship projects of the International AIDS Society. The principles, ethos and development of ILF are resolutely synonymous with the values of international co-operation enshrined by the IAS. I would like to thank my colleagues at the IAS and partner agencies for their enthusiasm and support. Most of all, I would like to thank all those who attend and contribute to the IAS-ILF. We share a collective goal – to increase and improve the capacity for research and treatment for the many populations who remain grossly under-served by the benefits of clinical progress. We look forward to a productive year in which fewer impediments and many more resolutions are secured.

Joep Lange, President, International AIDS Society

Scientific and clinical research that informs effective HIV therapy, promotes the up-scaling of treatment access and develops localised health care infrastructure remains integral to the health and economic regeneration of many countries in the developing world. The IAS Industry Liaison Forum emerged from a shared need identified by investigators, physicians and industry representatives that a number of confounding issues limit our potential for research success in resource-poor countries. At the same time, the role and responsibility of pharmaceutical and diagnostic companies with their intellectual and financial resource needed to be formally acknowledged and supported. A partnership forum that helped to mobilise this commitment and maximise our combined resources was established to consider and address these complex and inter-related issues. Planning, perseverance and a certain degree of prescience have all played a part in establishing an auspicious start to the work of the IAS Industry Liaison Forum. The commitment of the group to work both as a collective sharing expertise and the dedication of committed individuals devoting time and experience, has enabled the group to respond to some of the formidable challenges facing researchers in the developing world. As Chairs of IAS-ILF we have the privilege of witnessing, facilitating and contributing to this dynamic forum, nurturing collective consensus whenever and wherever possible. Many more challenges and resolutions have been identified then are contained here. The success criterion for the coming year is to continue to shape intelligent, resourceful and ethical responses to these dilemmas and identify emerging complexities. We would like to thank the many contributors and supporters for their continued commitment and invite them and newer members to collaborate in the future development and success of the IAS Industry Liaison Forum. As a membership forum, the direction and progress of IAS-ILF relies on the insight, diligence and commitment of its members.

Joep Lange, Michel Kazatchkine and Scott Hammer Co-Chairs, IAS Industry Liaison Forum

SUMMARY

The IAS Industry Liaison Forum (ILF) provides a co-ordinating role between industry, investigators and policy planners engaged with research in the developing world. The aim of IAS-ILF in conjunction with leading protagonists in health research is to identify and address key challenges in international medical research by promoting synergy in knowledge, practical experience and opportunity for sharing organisational resources and expertise.

Throughout the year, the IAS-ILF meetings have provided timely opportunities for discussion on issues, some more contentious, but all needing a consensual approach towards defining a baseline of agreement. The high-calibre of debate has been apparent from the many contributors from the developed and importantly the developing world who between them highlighted a range of issues pertinent to the conduct of research in the developing word. These included ethical considerations, modes of research, quality monitoring and global vigilance of generic compounds and the potential conflict of research paradigms when national treatment programmes are available. The focus throughout has been sponsor responsibilities; defining whom, to what extent and where possible, tangible propositions for advance.

The specific issue of post-trial care (PTC) provision was highlighted by the IAS-ILF membership as a key challenge towards ethical responsibility and potential for maximising future research conducted in resource-poor environments. Towards this end, a Consensus Framework on PTC has evolved from the ongoing discourse taking place between individuals and agencies involved with the IAS-ILF. It aims to provide a working strategy for consultation and agreement on the issue of PTC, and other issues related to HIV clinical care.

INTRODUCTION

The IAS Industry Liaison Forum forms part of a programme of initiatives established by the International AIDS Society. The IAS-ILF, co-chaired by Professor Joep Lange, President of IAS based in Amsterdam, Professor Scott Hammer, Chief of Division of Infectious Diseases at Columbia University, New York and Professor Michel Kazatchkine, Director of the National Agency for AIDS Research, Paris, has the specific aim of engaging with the pharmaceutical and diagnostic industry involved with HIV research in less-developed countries (LDCs).

The core membership and contributors to IAS-ILF reflect key stakeholders with active experience of research in LDCs including senior industry representatives, investigators from the developed and developing world and international research and policy agencies. In nurturing a dedicated forum for collaboration, the IAS-ILF seeks to identify , magor limitations that impede the development of further effective research and explore mechanisms for addressing these challenges. To date, the IAS-ILF has achieved the following:

— an important network of scientific industry representatives and experienced investigators from the developed and developing world — representation from senior officials involved with national research agencies including ANRS, MRC and ACTG — high level leadership and commitment from the IAS — active involvement of investigators from LDCs in its membership and discussion agenda — emphatic prioritisation of scientific and clinical research including ethical conduct — unique opportunity to influence industry in the sustainable investment of research capacity in LDCs

BENEFITS OF RESEARCH INVESTMENT IN RESOURCE POOR COUNTRIES

In countries where HIV has decimated already fragile economies, it is understandable that scientific enquiry may be superseded by other immediate priorities of welfare and survival. However, despite the lack of industrial infrastructure the urgency for providing effective health care is critical; indeed the availability of treatment is essential to the regeneration of these same communities. Medical research as a necessary correlate to treatment for HIV whilst widely recognised, still fails to attract adequate investment.

Research commitment even in the poorest regions of the world is a sound and logical contribution towards economic empowerment and health development. The UN General Assembly's Special Session (UNGASS) on AIDS in New York, 2001 culminated in a Declaration of international commitment to the compelling challenges of HIV infection and included as a leading priority "increased national and international investment in HIV/AIDS-related research and development [to] support and encourage the development of national and international research infrastructure, laboratory capacity ...develop and evaluate suitable approaches for monitoring treatment efficacy toxicity, side-effects, drug interactions and drug resistance..." (1)

The benefits available to sponsors and communities investing in health research in the context of LDCs are numerous and include:

— development of academic and teaching infrastructure — improved capacity for research with increased technological transfer and improved ICT — cultivating equitable partnerships as an integral element of clinical trial design and delivery — transforming research sites into treatment sites — benefits to research communities, not just research subjects — promoting access to treatment where availability and options for therapy are limited — addressing the burden of diseases particularly endemic in the developing world — epidemiological research essential for developing international health-policy — developing treatment paradigms and intervention strategies appropriate to local communities — increasing opportunities for registration of new drugs — promoting expert know-how and good clinical practice through increased presence of industry in LDCs — developing appropriately informed and ethical models for research

IAS-ILF SUMMARY HIGHLIGHTS 2002-2003

Since its inception, IAS-ILF has established an active and informed dialogue with leading investigators, physicians, industry scientists and policy officials from a wide range of organisations responsible for HIV research and treatment in resource-constrained countries. Such expert contribution has enabled IAS-ILF to identify priority issues of research including areas of clinical investigation that address specific concerns related to patient care in the developing world. A summary of these priority issues include:

— inequalities in standards of care between the North and South, but also regional differences within and between countries located in the Southern hemisphere — factors that facilitate or obstruct development of research including harmonisation of regulatory procedures, commercial and logistical transactions for distribution and supply, cohesive policy structures for the development and delivery of national treatment programmes — understanding cultural relativism of values and ethics and its impact on the design and execution of trials, on IRB membership and the criteria for defining success and relevance of research outcomes — commitment to different research structures and needs from Phase I to Phase IV studies, in particular the exacting challenges of regulatory trials aimed at product licensure — post-study considerations including roll-over to national treatment programmes, publication of research and criteria for post-study care — role of generic compounds as off-study treatment choices, for the management of co-morbidities and infections during the course of study and as potential post-trial treatment substitutes — the bioequivalence of generic drugs, need for consistent monitoring of quality, logistical supply and the problem of counterfeit drugs

A summary of outcomes from these discussions are listed below. Full minutes of the meetings and presentations are available from IAS-ILF coordinators.

ETHICAL CONSIDERATIONS

Situational differences in cultural values should be carefully understood and applied to research design and implementation including concepts such as universal versus contextual ethics and the importance of securing both individual and community consensus. IRB membership and decision-making should reflect local priorities and not impose values determined by sponsor agencies and countries. Standards of care (SOC) should be based minimally upon the WHO treatment guidelines but should consider local resources and be negotiated and agreed for each specific research community. We should be mindful of exacerbating inequalities in health

care through the introduction of resource-intensive research and treatment sites that benefit only a small section of the urban population. In practice, these should serve to throughput or catalyse other small-scale initiatives that can respond to the needs of the wider population. Whilst research priorities should reflect public health needs, research can only inform public health and not provide it. The provision of post trial care (PTC) should be demarcated from the responsibility to fund PTC. Sponsors should not necessarily incur the full and sole responsibility for resourcing PTC and other research related costs. But sponsors do have ultimate responsibility for ensuring that PTM can be ethically delivered before embarking on the research activity. Informed consent that requires a priori agreement with patients to forgo future treatment is not acceptable.

DESIGN AND LOCATION OF RESEARCH

We should reconsider our criteria for 'best science' and definitions of research success in the context of local population needs and circumstances. Commitment to research should reflect the full spectrum of research needs from Phase I to Phase IV and include clinical, epidemiological and implementation research. Where registrational trials are conducted, company sponsors should be required to pursue approval in the country of research. Commitment should be made to positively influence the development of national treatment programmes and health service infrastructure wherever possible as a corollary to effective research. Research sponsors may benefit from preferentially locating research in countries with government endorsed national treatment programmes and co-operative public health infrastructure. This may help address both the ethical need for continued treatment whilst also providing alternative therapy options for patients experiencing adverse events. The growing expertise of investigators located in the South needs to be more formally recognised and increasingly included in the planning, delivery and dissemination of research undertaken in the developing world. Research and laboratory expertise should be considered for development on a regional basis; allowing for laboratories

for example to concentrate resource on specialist scientific areas and sharing these across localities. Minimum or baseline standards for research including data collection, research methodology and analysis should be developed to optimise the research learning process. Research sites need to focus not only on their own investigational needs but pre-emptively establish constructive partnerships with other local organisations and partners for effective delivery of research and continued benefit to local communities. Need to share expertise in costing and planning research including resourceful strategies for sampling, collection and retrospective analysis. Minimal baseline standards need to be developed and agreed for the use and application of diagnostic technology. The development of rational diagnostic infrastructure should be considered an essential pre-requisite to effective research. Development of low-cost diagnostics should be encouraged during research planning that will serve local communities beyond the life of the research.

QUALITY SURVEILLANCE FOR GENERIC COMPOUNDS

Need to deploy accurate descriptions to distinguish between generics, copies, similars, dissolution data and bioequivalence. Pharmacology studies urgently needed to determine bioequivalence of available generics. Responsibility for quality monitoring of generic drugs to international standards set by WHO should be vigorously maintained. Quality surveillance of generics should include candidates for paediatric formulations.

Barcelona, July 2002 and Boston, February 2003

NATIONAL CONSIDERATIONS FOR POST-TRIAL CARE

Ernest Darkoh,
Ministry of Health, Botswana

Key observations

Highlighting disparities between national treatment and research priorities in Botswana, where patients may be more likely to come forward for recruitment to trials rather than seek independent testing and treatment from the country programme. The reasons for this include stigma associated with HIV status resulting in many patients presenting with advanced disease and low CD4 counts. Patients may also prefer to enrol for trials in order to benefit from the increased time and exposure that they would receive from health-care staff as well as the additional counselling and diagnostic support made available.

ethical and practical complications that arise for subjects at the completion of a trial, namely:

should patients automatically qualify for the national treatment programme as a mechanism for securing PTM?

should patients be rolled-over to other research or cohort studies or 'handed-over' to the national programme?

should study subjects be allowed priority access to the national treatment programme thereby 'jumping the queue' against others not enrolled in studies but who may have legitimate need for treatment?

should individuals identified for studies but not eligible for the specific trial criteria be prioritised for the national treatment programme if they are in need of HIV therapy?

implications for switching from the trial regimen to the national SOC which may differ

Paris, July 2003

QUALITY MONITORING OF GENERIC DRUGS

Terrence Blaschke, Professor of Medicine and Molecular Pharmacology, Stanford University

Despite dramatic reductions in the pricing of many licensed antiretroviral therapies for use in the developing world, the cost of HIV therapy still prohibits the widespread treatment of many in countries where health expenditure per capita remains grossly inadequate.

Whilst generic drugs may appear to offer a convenient panacea with prices often at a mere fraction of their patent equivalent, confounding factors complicate the issue of generic compounds. Even obviating the pressing issues of patent laws, intellectual property and licensing rights, the critical factor that determines purchase and use of drugs manufactured outside of the countries participating in ICH activities is that of drug quality.

Confounding factors

Major differences in the capacity of countries to regulate pharmaceuticals
Many countries have either no requirements for export of drugs or the quality requirements for export are not rigorous.
Lack of government expertise in regulatory sciences and GMP in many countries.
Significant financial incentives for diversion or for re-importation of ARVs.
WHO has a comprehensive set of guidelines but the degree of implementation varies from country to country.

Defining generics

By definition, a generic drug is a medicinal product that contains the same quantity of active ingredient in the same formulation as the innovator or brand name reference product. The FDA definition of generics is somewhat distinct from the term used to describe generic drugs in the situation of the developing world. In this setting, generic applies to all drugs both on and off-patent that are manufactured outside the USA and sold usually at lower cost to NGOs and various ministries of health.

The approval process for generic compounds involves submission of an Abbreviated New Drug Application (ANDA) that requires: chemistry, manufacturing, controls, labeling, testing and bioequivalence. If bioequivalence can be demonstrated the approval does not require evidence of efficacy.

The terms bioequivalence and bioavailability are distinctly separate and describe pharmacologic formulation but also refers to the terminology utilized by regulatory authorities. For regulatory purposes, bioequivalence defines the similarity in plasma concentration-time profiles considered to provide evidence of equivalent drug efficacy compared to the brand name drug. Whilst the degree of similarity determined clinically may be considered somewhat arbitrary, the demonstration of bioequivalence requires in almost all cases a human in vivo study comparing plasma concentration between the generic and the brand name drug, usually through single-dose crossover studies in healthy volunteers measuring Cmax and AUC parameters. For generic products to be defined as bioequivalent they have to be pharmaceutically and therapeutically interchangeable with innovator products in their content, administration, efficacy and safety profile.

WHO Pilot Procurement, Quality and Sourcing Project

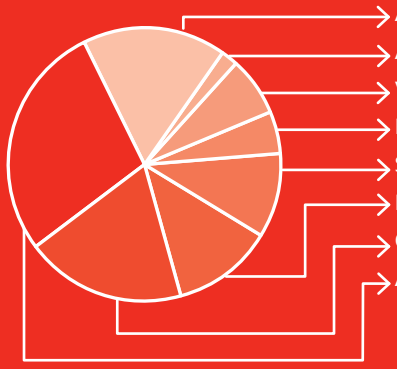
The World Health Organisation (WHO) HIV/AIDS Drugs Pre-qualification Pilot Procurement, Quality and Sourcing Project: Access to HIV/AIDS Drugs of Acceptable Quality is responsible for the evaluation of product data and GMP inspection

of manufacturing sites that produce generic compounds. In addition to the interchangeability profile, the WHO Guide on Requirements for Documentation of Quality For Pharmaceutical Products Related to HIV and AIDS require manufacturers to provide a detailed review of their product including the manufacturing process, stability testing, specifications of active ingredients, excipients, package labeling and toxicology.

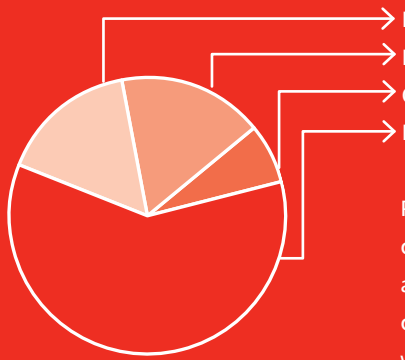
Drug quality

The issue of drug quality has major implications for effective clinical care. Historical experiences with substandard or counterfeit drugs confirm either poor or no therapeutic benefits or in extreme cases have resulted in patient deaths.

Paris, July 2003



Classes of drugs reported as counterfeit between Jan 00 and Dec 01



Percentage breakdown of data on 325 cases of substandard drugs – including antibiotics, antimalarials and antituberculous drugs reported from around the world to WHO database
Source: Dr Lembit Rägo WHO – EDM

CRITERIA FOR POST-TRIAL CARE

Purpose for Establishing PTC Framework

An informed Consensus Framework for PTC can provide investigators and key stakeholders with guidance on primary responsibilities associated with the co-ordination and delivery of post-trial care for participants engaged with trials in resource-poor countries. The PTC criteria seeks to promote the incorporation of post-study care as an integral component of international health research and develop appropriate strategies for ensuring that consensus criteria are explored and duly addressed through developments in policy and practice.

A central tenet of the Consensus Framework is the right to health and the equitable engagement between researchers from the developed and developing world; to nurture intellectual talent, develop capacity for research and promote broad dissemination of research findings.

Objectives for securing post-trial medication and care

The PTC framework outlines a number of principal objectives whilst not exhaustive, are key to securing an effective minimal criteria for post-trial medication and care:

— defining the post-trial period and conditions including a minimal time-scale for provision of PTC — establish minimal standards of care (SOC) and treatment algorithm for PTC — identifying responsible individuals and teams for communication, management and delivery of PTC — continuing research through roll-over, cohort and operational research wherever possible — harmonisation of administration, operational management and registration of drugs

post-trial — preferential location of research investment in regions with some level of health and delivery infrastructure

The ILF membership firmly believes that while the issue of defining responsibilities for post-trial medication and care remain ad hoc and ambiguous, many potential sponsors for research may feel under pressure to limit rather than expand their research investments in the developing world. In the absence of an official organisational response to defining criteria for post-trial care, ILF is keen to frame suggested guidance on this issue. The ownership and responsibility for adhering to such guidance rests with individuals and agencies undertaking research in the context of LDCs.

By detailing the challenges and agreement to the following objectives and defining responses to the statements outlined, the ILF aims to develop a recommended strategy for promoting effective approaches to the provision of PTC in the developing world.

Defining Post-Trial Care

Post-trial medication and care refers to the continuity of treatment and medical care made available to individuals who have participated in a clinical research at the formal completion of a research trial. PTC needs to be made available to participants regardless of the length, format, location and aims of the study and based on the proven efficacy of the intervention investigated.

Requirement for PTC is based on the ethical responsibility of compensating individuals who voluntarily expose themselves to potential risks including drug-related toxicity and who sacrifice time, make personal commitments and suffer inconvenience of invasive procedures, intrusive scrutiny or constraints on their behaviour and lifestyle and possible negative impact on health status.[2] The key principal responsibility for PTC however, is based upon the fact that

research subjects in the setting of LDCs may not receive the final product through the usual health care process, or indeed may possibly not receive any health care at all once the trial is complete.

As well as study subjects, potential beneficiaries to successful research include principal investigators, research teams, study sponsors including those benefiting from potential commercial successes whether the projected markets are within or beyond the location of the study. Wider benefits also accrue for governments, international research agencies, community representatives through positive impact on individual and community public health. As such, all direct and indirect beneficiaries should define and consider specificity and degrees of responsibility for ensuring that PTC is made available in each commitment to research and is delivered appropriately and efficiently within the terms predefined. However, the pecuniary commitment for PTC should be met by those most closely benefiting from the research either commercially as in the case of industry sponsored research or shared, where the research outcomes address the goals of government and international aid agencies.

It is agreed that all post-trial considerations should take place before the trial commences; early negotiations and agreements are critical determinants in the success of achieving post-trial welfare for subjects.

In the absence of a universal consensus on the definition and parameters of PTC, the ILF suggest a number of considerations as a basis for consultation and agreement between key stakeholders actively involved or with due responsibility for maximising research in resource-poor countries.

Defining the post-trial period

Based on good practice and experience of investigators from leading international research

initiatives, the ILF has agreed that a minimal commitment of two years therapy post-trial would suffice as reasonable. Provisions for this must be negotiated and secured before the trial between the sponsor and host agents and clearly specified in the patient consent forms.

Establish minimal SOC and conditions for PTC

Constituents of an effective regimen for PTC should be based upon the WHO guidelines for treatment; the PTC statement should define the drugs and minimal diagnostic support that will be provided. Optimal algorithms for switching drugs utilised in PTC in cases of drug related side-effects and intolerability should also follow the WHO guidelines for treatment.[3]

Determinants of failure should be agreed before embarking on a programme of PTC and should identify whether virologic, immunologic or clinical indices will be used to measure failure. A reasonable degree of contingency planning for technical complications such as non-delivery and poor storage conditions should be clearly defined in the statement of PTC.

Point of delivery for PTC should be considered to allow patients to receive PTC from the same research site or if more convenient, from local sites for pharmacy dispensing and clinical vigilance. Compensation for patients should not only define PTC as pure medical costs but consider other forms of support that may be critical in promoting treatment success such as travel and subsistence that was provided during the course of the study.

Location of research

The availability of alternative treatment options provided by national treatment programmes may provide additional safety and benefit for patients enrolled on clinical trials. Locating research in countries where national treatment programmes are available may help to mitigate the ethical constraints of coercion arising from the need for continued treatment or addressing adverse events during the course of the trial. Investigator reports allude to patients on trials

experiencing drug-related adverse events, either noted by the investigators or not disclosed by the patient for fear of exclusion from the study. It is recommended therefore, that new IND studies should be undertaken in settings where alternative treatment options are available.

Strategies for patient roll-over to other studies or treatment programmes

Strategies for patient roll-over to other studies should be carefully determined; this will involve co-operative networks and reciprocal collaborations between researchers in the same region or working on similar scientific investigations. There should be an ethical and practical requirement to ensure that trials with agreed PTC framework should be preferentially located in countries where there is a genuine government-endorsed programme for antiretroviral treatment. Negotiations with health ministries should be conducted to ascertain the relevance to public health and consequent access to national treatment programmes as roll-over from studies or following the termination of PTC.

Treatment for family members and dependents of subjects enrolled in trials

Treatment of family dependents not associated with the research study has emerged as a contentious issue with many experts defining this as beyond the scope of responsibility of study sponsors. However, as good practice, where this is possible or national treatment programmes available, this should be carefully considered. The rationale for providing treatment to additional family members is to mitigate inequality and potentially disruptive consequences between research subjects and their family members equally deserving, but not recruited for study. Secondly, this commitment acknowledges the harsh reality that without this provision, research subjects may be unduly influenced to share their medication with others in the family who are in urgent need of treatment. [4]

Clarifying sponsor responsibilities

Given the complexity and detail of responsibilities, lead sponsor and contributors' responabilities need to be carefully considered and concomitant responsibilities pre-emptively stratified. Where industry has initiated trials, particularly for the purposes of registration, the legal responsibilities of the research-sponsor are stringently defined and monitored. This may become more obtuse when companies are supporters or contributors to research instigated by other international research bodies. In the case of the latter where industry offer to supply the necessary drugs to external researchers, experience has shown that deficiencies in project management resulting in inadequate or incomplete study outcomes may reflect negatively on industry contributors.

Cost and administration of PTC

The funding of post trial medication and care is dependent upon three criteria: who will pay, responsibilities of national governments through emerging treatment programmes and mechanisms for establishing a pre-study intention or statement for PTC that clearly states the agreed responsibilities and benefits between sponsors and research teams.

A pre-study contractual statement for PTC should:

— define the cost of providing PTC per subject per trial — calculate projected expenditure based on full extent of PTC funding including associated responsibilities — define who will take sole or shared responsibility for PTC and develop a sliding-scale of beneficiaries and attendant responsibilities — ascertain feasibility of roll-over and cohort studies as a means of continuing therapy — negotiate specific policies that assign responsibility for national governments and state authorities to provide PTC for research conducted in their country — develop models for calculating the potential demand for PTC based on projected modelling strategies

IAS-ILF POST-TRIAL CARE CONSENSUS FRAMEWORK

Treatment to be made available for a minimum of two years following completion of trial

Standard of care for PTC to meet WHO treatment guidelines

Treatment failure to be based on clinical criteria unless diagnostic resources are available

Use of generic drugs in PTC not advised to mitigate the concern of drug quality

Treatment of family members need not be defined as responsibility of study sponsors

PTC period should be used to promote continuing research

Research to be preferentially located in countries with national treatment programmes

Less-intensive strategies for clinical management should be deployed for PTC delivery

IAS-ILF should liaise with key stakeholders to facilitate implementation of PTC strategies

Pre-study contract should clearly detail all responsibilities and demarcations for PTC

FORWARD PLANNING

The aim of the IAS–ILF in the coming year is to continue to pursue challenges to scientific, clinical and implementation research in LDCs. As a more established entity, the IAS–ILF can also develop its role as advocate and mediator to militate initiatives for effective research. By providing a cohesive and leadership role, the IAS–ILF is able to develop thematic priorities as articulated by its membership. Of note, a number of key priorities have emerged including treatment of paediatric patients, exploiting novel treatment strategies and mechanisms for optimising operational research to deliver localised health care services.

Practically, IAS–ILF will continue to:

— organise bi–annual meetings of IAS–ILF to coincide with high–profile meetings on the international HIV conference calendar including IAS International Conferences — plan meetings between ILF Co–Chairs and individual companies to provide further opportunities for confidential dialogue and address specific company concerns — invite policy planners to negotiate identified challenges — develop IAS–ILF as expert advocate on planning and implementation of research in LDCs — define, monitor and evaluate outcomes as agreed by ILF membership — safeguard the autonomy and independent status of the IAS–ILF — maintain accountability to its membership and to the IAS — establish a core group of supporters from the membership for targeted consultation

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